Remarks

Claims 15, 17, 18 and 20-25 were pending in the subject application. By this amendment, claims 15 and 17 have been amended, claims 22-25 have been cancelled and new claims 33-38 have been added. The applicants have also cancelled claims 26-32 as being directed to non-elected subject matter. Support for the amendments and new claims can be found throughout the application including at, for example, page 1, first paragraph; page 2, first paragraph; page 4, first full paragraph, third full paragraph, and fourth full paragraph; and page 9, second full paragraph. No new matter has been added by these amendments. Accordingly, claims 15, 17, 18, 20, 21 and 33-38 are currently before the Examiner for consideration. Favorable consideration is respectfully requested.

The amendments presented herein have been made to lend greater clarity to the claimed subject matter and to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 15, 17, 18 and 20-25 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fong (*The Journal of Infectious Diseases,* 2000, Vol. 181, Suppl. 3, pp. S514-S518) in view of Vlasselaer *et al.* (US 2001/0043906). The applicants respectfully traverse this ground for rejection because the cited references, taken either alone or in combination, do not disclose or suggest the use of an anti-infective agent to reduce lethality and morbidity in patients who have just had a stroke.

The method of the present invention involves the administration of an anti-infective therapy to a patient shortly after that patient has suffered an acute stroke. The therapy is applied soon after the occurrence of the stroke and is applied, contrary to the teachings of prior art, even in the absence of an established infection. Surprisingly and advantageously the method of the subject invention reduces lethality and morbidity in stroke patients.

The Fong reference pertains to the use of moxifloxacin for the prevention of atherosclerotic lesions of the aorta following an infection (see page S516, left column, first full paragraph). The teachings of Fong may be relevant for efforts to develop treatments against atherosclerosis for patients suffering from chronic bacterial infections but they are not relevant to patients who have just

suffered a stroke. Specifically, Fong does not disclose or suggest a method of treatment following an acute stroke in a patient not having a pre-existing chronic infection.

Fong refers to the effects of antibiotics in a rabbit model of Chlamydia pneumoniae-induced atherosclerosis (see, for example, the title). The idea underlying the study performed by Fong is that "chronic bacterial infections may be strongly associated with the development of CHD (coronary heart disease) or stroke. "(parenthesis added, see page S514, left column, first paragraph of Fong). The above-cited text, together with the first sentence of the abstract, are the only references in the entire article referring to stroke. Otherwise, the article focuses on effects achieved by administering antibiotics to rabbits suffering from atherosclerosis due to an infection with Chlamydia pneumoniae.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ (2007). In this case, the applicants respectfully submit that there is no reason to modify the cited references to arrive at the current invention and, thus, there is no *prima facie* case of obviousness.

Since Fong does not make reference to stroke except as indicated above, a person of skill in the art would have had no motivation to link the teachings of Fong with a method for anti-infective therapy after acute stroke. Also, unlike the teachings of Fong, the present invention is not related to chronic infections that are present before a stroke occurs.

Vlasselaer *et al.* teach administration of gamma-interferon in liquid-droplet aerosol form. Again, the treatment described by Vlasselaer *et al.* is predicated on the pre-existence of a condition or infection. Vlasselaer *et al.* do not disclose or suggest a method of treatment following an acute stroke in a patient not having a pre-existing chronic infection.

Further, it is incorrect to state that Fong, teaching the use of antibiotics, and Vlasselaer *et al.*, teaching the use of interferon-gamma would in combination produce the present invention. The teachings of both of these references are restricted to treatment of a condition after specific symptoms have arisen. In contrast, according to the present invention, the anti-infective agent is administered before the onset of symptoms for an infective disease and without a chronic disease being already present in the patient.

In order to underscore that the results of the present invention are surprising, please consider the attached excerpt from "ScienceDaily" dated October 5, 2007, which reports that patients being treated with an antibiotic shortly after suffering a stroke had significantly fewer disabilities. Please note that this treatment was considered both newsworthy and "new" (see the title), thus providing objective evidence of the surprising nature of the current invention.

Thus, in the current case, the cited references, either taken alone or in combination, do not disclose or suggest the applicants' advantageous method of treating stroke wherein lethality and morbidity are reduced by administering an anti-infective agent shortly after a stroke occurs. Therefore, the applicants respectfully request reconsideration and withdrawal of the obviousness rejection under 35 U.S.C. §103 based on Fong in view of Vlasselaer *et al.*

In view of the foregoing remarks, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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DRS/jil-la

Attachments: 1) Copy of ScienceDaily, October 5, 2007, "New Treatment For Stroke Works Up To A Day After Symptoms Start"
2) Request for Continued Examination (RCE)

Science News

New Treatment For Stroke Works Up To A Day After Symptoms Start

ScienceDaily (Oct. 5, 2007) — People treated with the drug minocycline within six to 24 hours after a stroke had significantly fewer disabilities, according to a study published in the October 2, 2007, issue of Neurology®, the medical journal of the American Academy of Neurology.

See also:

Health & Medicine
- Elder Care
- Stroke Prevention
- Diseases and Conditions

Mind & Brain
- Caregiving
- Stroke
- Brain Injury

Reference
- Multi-infarct dementia
- Brain damage
- COX-2 inhibitor
- Hormone replacement therapy

Researchers say minocycline may be an alternative treatment for stroke because current treatments only work during the first few hours after the onset of symptoms, and many people don't get to the hospital in time to be treated.

For the study, 152 men and women received either an oral dose of minocycline or placebo for five days following stroke. People who received minocycline were treated an average of 13 hours after stroke compared to 12 hours for the placebo group. Researchers followed both groups for three months.

The study found people treated with minocycline had significantly better outcomes than those treated with placebo. After three months, the minocycline group performed four times better than the placebo group on the National Institutes of Health Stroke Scale, which measures vision, facial palsy, movement, and speaking ability. The minocycline group received a score of 1.6, which indicates little or no disability, compared to a score of 6.5 for the placebo group, which indicates a high end of mild disability.

"The improvement was already apparent within a week of the stroke," said study author Yair Lampl, MD, with Edith Wolfson Medical Center and Tel Aviv University in Israel. "This is exciting because many people who have had stroke cannot be treated if they don't get to the hospital within three hours after symptoms start, which is the time frame for current available treatments."

"While these are promising results, a much larger, closed-label, study is needed to confirm our findings," said Lampl. "Further research is also needed to look at whether the dosage of the drug taken in this study is optimal and whether giving the drug through an IV would be more effective."

Lampl says the improvement shown by patients taking minocycline is not due to the drug's basic antibiotic effect, but rather its anti-inflammatory effect and ability to protect brain cells from destruction. Minocycline has already been shown in other studies to have a neuroprotective effect in animal models of multiple sclerosis, Parkinson's disease, Huntington's disease, and Lou Gehrig's disease, or ALS.

Lampl says none of the participants experienced any serious side effects from the drug.

Adapted from materials provided by American Academy of Neurology.

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